Dimensional characteristics of FDM 3D printed PEEK implant for craniofacial reconstruction

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Abstract: Additive manufacturing (AM) or three-dimensional (3D) printing is rapidly gaining acceptance in craniomaxillofacial surgeries. Polyetheretherketone (PEEK) patient-specific implants (PSIs) have been used, mainly in reconstructive surgeries, as a reliable alternative to other alloplastic biomaterials. With the use of Fused Deposition Modeling (FDM) 3D printing technology, complex anatomical shaped PEEK PSIs can be fabricated within a clinically acceptable dimensional accuracy range and in a short time-frame. This aspect paves the way for prospective clinical applicability, especially in an in-house 3D printing set-up, where hospitals can utilize this digital AM workflow to provide personalized treatments cost-effectively.

I. Introduction

The rapid acceptance of additive manufacturing (AM) or three-dimensional (3D) printing in the healthcare sector has revolutionized the modern practice of personalized medicine. The refinement in 3D printing technologies, coupled with the capability to produce patient-specific implants (PSIs), has given rise to a proliferation of alternatives to conventional implants [1].

There is an exponential research on the techniques to provide personalized treatment in craniomaxillofacial surgeries utilizing various 3D printing technologies and materials. Polyetheretherketone (PEEK) has been used, mainly in reconstructive surgeries, as a reliable alternative to other alloplastic materials. Furthermore, technological advancements in extrusion-based Fused Deposition Modeling (FDM) 3D printers have made it conceivable to process high-temperature thermoplastics material such as PEEK. With rapid evolution in this field, FDM 3D printers are currently being developed specifically for medical PEEK applications [2,3].

Considering the prospective application potential of FDM technology in craniomaxillofacial surgeries, this work was conducted. Here we present a method in the evaluation phase of an FDM 3D printer to fabricate complex anatomically shaped PEEK PSI. The potential clinical applicability of this digital AM workflow was accessed regarding an exemplary cranioplasty case.

II. Material and methods

II.I Preoperative computational image acquisition and virtual surgical planning:

The skull of a patient was scanned using a high-resolution computed tomography (CT) (*Fig. 1a*). The Digital Imaging and Communications in Medicine (DICOM) data was then imported into a medical imaging software (MIMICS 21.0, Materialise, Leuven, Belgium) (*Fig. 1b*). Threshold selection was done using bone-specific Hounsfield units to mark the skull region. Using a semiautomatic segmentation protocol, a 3D volumetric reconstruction of the skull was generated (*Fig. 1c*). For precise reconstruction of cranial prosthesis, a computer-aided design (CAD) modeling software was used (3-matic medical 13.0, Materialise, Leuven, Belgium) (*Fig. 1d*). The virtually planned file of cranial prosthesis was exported in a Standard Tessellation Language (.STL) format for 3D printing.

II.II FDM 3D printing of PEEK cranial prosthesis:

The .STL file of cranial prosthesis was imported into 3D slicing software (Simplify3D 4.1.1, Simplify3D, Cincinnati, USA), and the corresponding G-code data was transferred to the 3D printer (*Fig. 1e*). The FDM 3D printer selected for the printing process was Kumovis R1 (Kumovis GmbH, Munich, Germany). The filament used was a natural 1.75 mm, unfilled PEEK filament (KetaSpire® PEEK AM Filament MS-NT1, Solvay Specialty Polymers, USA). The printer had a single extruder with a nozzle diameter of 0.4 mm, and the fabrication of PEEK PSI was accomplished at a processing temperature of 420^{0}C.

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II.III Assessment of dimensional accuracy and deviations in FDM 3D printed PEEK cranial prosthesis:

The fabricated PEEK PSI was digitized using an optical-based scanning system (EinScan-SE, SHINING 3D Tech. Co., Ltd., Hangzhou, China) and the generated 3D point cloud data was converted into STL file format. To evaluate the dimensional deviations and assess the overall accuracy of fabricated PEEK PSI, a 3D part comparison analysis was done (3-matic medical 13.0, Materialise, Leuven, Belgium). Interactive closest point algorithm was used to calculate the closed point distance between the two-3D surface meshes (planned and actual). A color-coded surface distance map was used to examine the qualitative and quantitative congruence or incongruence between planned and actual FDM printed PEEK PSI. The root mean square (RMS) value was used to quantify the overall 3D deviations.

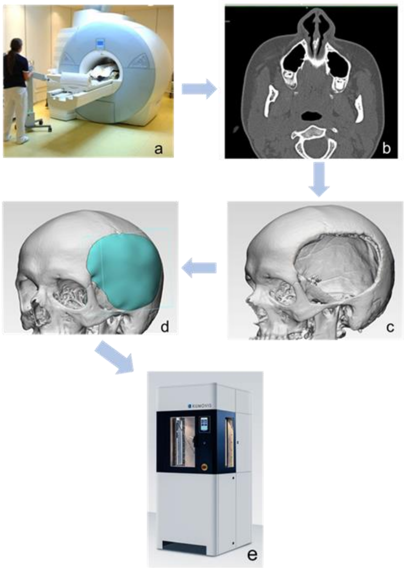

Figure 1: Schematic representation of a digital AM workflow in an exemplary cranioplasty case (a) CT scan, (b) DICOM import, (c) Segmentation, (d) Virtual surgical planning and designing of cranial prosthesis, (e) Transfer of files to FDM 3D printer for fabrication of PEEK cranial prosthesis.

III. Results and discussion

The preliminary results show that the PEEK PSI had a smooth surface finish displaying no stair-stepping effect (*Fig. 2b*). A common concern in FDM PEEK printing is improper crystallization of the part resulting in delamination. The enclosed build chamber and heated build platform of the printer provided optimal thermal distribution, and the fabricated prosthesis was without any signs of delamination, warpage, and discoloration (a sign of improper crystallization). The total time duration in the virtual surgical planning phase was 50 mins, followed by 200 mins for 3D printing of cranial prosthesis.

The comparative color-coded surface map illustrates that slight negative and positive deviations were noticed on the squamous (outer) and cerebral (inner) surface of the PSI, respectively (Fig. 2c). To minimize the post-processing procedures, the PSI was printed in a vertical orientation. This probably explains the slight deviations noticed at the high curvature regions of the PSI, which were without support structures. The quantitative assessment for dimensional accuracy revealed a mean difference ± SD of 0.03 ± 0.60 mm, median difference (Q1 to Q3) of -0.02 (-0.30 to 0.22) mm, an RMS value of 0.60 mm. These results illustrate that the overall dimensional accuracy of the exemplary FDM 3D printed PEEK PSI was within the clinically acceptable range for craniofacial reconstructions.

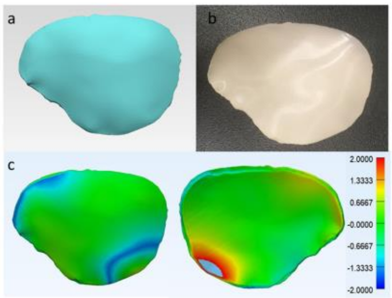

Figure 2: Assessment of dimensional deviations and overall accuracy of FDM 3D printed PEEK cranial prosthesis (a) CAD of virtually designed prosthesis, (b) FDM 3D printed PEEK cranial prosthesis, (c) Color-coded map depicting deviations in the cranial prosthesis.

IV. Conclusions

Within the scope of this work, the illustrated digital AM workflow shows that the fabrication of PEEK PSI based on complex anatomical structures can be accomplished within a short time-frame (< 24 hours) and hence, provides a faster implant production. This provision of personalized medical implants can help in cost reductions for hospitals in many ways, including shorter preoperative planning and surgery times, postoperative complication reduction, and shorter patient hospitalizations. However, to comprehend the future potential of this technology, future studies are essential regarding the reproducibility and biomechanical behavior of these implants.

Furthermore, compliance with specific regulatory guidelines should be followed for the fabrication of implants in a hospital environment. Integration of standardized operational measures such as quality management protocols should be implemented to maintain the manufacturing quality of the implants fabricated inside hospitals.

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AUTHOR'S STATEMENT

The authors state no conflict of interest.

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